**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF VIRGINIA**
**(Alexandria Division)**

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| **UNITED STATES OF AMERICA, *et al.*,** | |
| **Plaintiffs,** | **CIVIL ACTION NUMBERS:** |
| | **1:09-cv-0013 (CMH/TCB)** |
| **v.** | **1:11-cv-1054 (CMH/TCB)** |
| | **1:14-cv-1228 (CMH/TCB)** |
| **HCR MANORCARE, INC., *et al.*,** | |
| **Defendants.** | |

**DEFENDANTS HCR MANORCARE, INC., MANOR CARE, INC., HCR MANORCARE SERVICES, LLC, AND HEARTLAND EMPLOYMENT SERVICES, LLC'S MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS THE COMPLAINT OF THE UNITED STATES**

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Defendants HCR ManorCare, Inc. ("HCR ManorCare"), Manor Care, Inc. ("Manor Care"), HCR ManorCare Services, LLC ("HCR Services"), and Heartland Employment Services, LLC ("Heartland Services") (collectively "HCRMC" or "Defendants") submit this memorandum in support of their Motion to Dismiss the Complaint of the United States pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b).

## I. INTRODUCTION AND SUMMARY OF ARGUMENTS

This action purports to allege violations of the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA") and federal common law claims of unjust enrichment and payment by mistake based on the alleged over-delivery of rehabilitation therapy to Medicare and TRICARE patients. Medicare Part A provides a guaranteed benefit that includes rehabilitation therapy to which eligible patients are entitled by law. *See* Medicare and Mayberry, White House Blog (July 30, 2010), www.whitehouse.gov/blog/2010/07/30/medicare-and-mayberry (describing Medicare benefits as "guaranteed").[1] The Centers for Medicare & Medicaid Services ("CMS") have empowered physicians to authorize, and licensed therapists to determine, the appropriate amount of Medicare Part A rehabilitation therapy for each patient. Both Congress and CMS have declined to define the appropriate level of therapy other than to require that the therapy be reasonable and necessary. As such, the Complaint is based on the government's *post hoc* disagreements with clinical determinations regarding levels of rehabilitation therapy services provided pursuant to orders issued by licensed physicians and assessments conducted by licensed therapists over the course of nearly six years. The Department of Justice's Complaint is contrary to the explicit provision of a regulation issued by CMS which established that clinical disagreements regarding rehabilitation therapy assessments do not constitute material and false

[1] Regulations for billing and payment of TRICARE rehabilitation claims are essentially the same as those for Medicare Part A. *See* Compl. ¶ 67.

statements. *See* 42 C.F.R. § 483.20(j)(2).

HCR ManorCare, through individual subsidiaries, pursuant to lease agreements with owners, contracts to operate 281 skilled nursing facilities ("SNFs") in approximately 30 states. These SNFs provide specialized and individualized in-patient treatment for patients covered by private and government insurance programs who are recovering from surgery, illness, or injury following hospitalizations, including intensive rehabilitation treatments to help patients resume their pre-hospitalization level of function. Each SNF is staffed by licensed therapists who make individual determinations regarding the appropriate level of rehabilitation therapy required to address the unique needs of each patient based on the orders of their treating physician. CMS places responsibility on the treating physicians, nurses and therapists in each SNF to make clinical judgments that result in the placement by the government of each Medicare or TRICARE patient into one of twenty-three different rehabilitation reimbursement levels that can change multiple times during a single SNF stay. It is HCRMC's responsibility to deliver the level of therapy to which each patient is entitled by law.

The Complaint alleges that HCR ManorCare and three corporate subsidiaries knowingly submitted fraudulent claims to the government for reimbursement of therapy services. The government maintains that the claims were false because HCRMC provided ***too much*** rehabilitation therapy to an exceptionally small number of the over one million rehabilitation patients who were treated at HCRMC facilities during this six-year time period. Despite the fact that these claims were contemporaneously approved and paid, the government now claims that these allegedly excessive services resulted from purported corporate pressure on therapists to maximize reimbursement. Significantly, the government does not allege that these services did not benefit the patients or that HCRMC did not incur the costs of providing these services, but

rather now asserts that it should not have to pay for the entirety of treatment HCMRC provided to each patient. This is no different than retroactively telling Medicare Part A participants that the government will not pay for an arbitrary portion of what is supposed to be a guaranteed benefit.

The Complaint does not identify or individually accuse any clinical professionals of fraud, but instead alleges that collective actions of these unnamed professionals constituted fraud by HCRMC. The government claims that unidentified senior corporate officials caused unidentified physicians to order, and unidentified licensed therapists to provide, unnecessary rehabilitation therapy.[2] The Complaint does not identify a single conversation between a corporate officer or official and a physician or therapist in furtherance of this alleged activity. The Complaint does not identify a single physician or licensed therapist who agreed to participate in this alleged activity. Instead, the Complaint simply cites to sentences extracted by the government from random documents prepared by low-level or mid-level employees relating to budget and management issues that not only contain no evidence of any agreement to commit fraud, but are also not in any way connected by the government to the patients listed in the Complaint. That is, the Complaint does not allege that any of the unnamed individuals who delivered therapy to the patients listed in the Complaint ever read, had access to, or knew anything about the information contained in these random document extracts. Moreover, the cited documents are for the most part nothing more than legitimate business metrics showing that HCRMC implemented prudent business practices.

[2] The Complaint does not identify who employed each of these unnamed physicians. Further, although the Complaint generally alleges that Defendant Heartland Employment Services, LLC leases employees, including therapists, to HCRMC SNFs, it does not distinguish between corporate employed and contract therapists who are not directly employed by any Defendant.

These deficiencies create at least two insurmountable obstacles here that courts have found fatal in similar recent cases brought by the government. First, the documents referenced in the Complaint are valid business metrics used in the normal course of operations and are not evidence of fraud. *See United States ex rel. Lawson v. Aegis Therapies*, No. 10-0072, 2015 WL 1541491, at *30-33 (S.D. Ga. Mar. 31, 2015) (granting summary judgment for defendants, and finding that corporate pressure to achieve benchmarks was not evidence of fraud, but rather evidence that "defendants employed prudent business practices") (attached as Exhibit A). Second, because these documents do not relate to any specific patient or claim set forth in the Complaint, they do not support a reasonable inference that any particular claim was false. *See United States ex rel. Paradies v. Aseracare Inc.*, No. 12-245 (N.D. Ala. May 20, 2015) (ordering bifurcation of trial and requiring the government to prove objective falsity of each individual claim before jury can consider general corporate pattern and practice evidence) (attached as Exhibit B).

Importantly, the Complaint also ***does not*** allege: (1) that HCRMC submitted claims for services that were not actually provided to patients; (2) that HCRMC billed for services provided to patients who were ineligible for rehabilitation therapy; (3) that HCRMC failed to comply with physician certification requirements for rehabilitation therapy; (4) that HCRMC delivered rehabilitation therapy in excess of the level ordered by and determined to be medically necessary by physicians; (5) that HCRMC fabricated medical records documenting patients' conditions, therapy or progress; (6) that HCRMC billed for fictitious patients; or (7) that the government previously denied claims submitted by HCRMC and as such HCRMC should have been on notice of the alleged provision of excessive therapy.

Critical to this case is the interpretation of hundreds of pages of statutes, regulations,

rules and guidance from the government regarding eligibility and billing for rehabilitation therapy. This material is general in form and content, and does not provide objective guidance capable of after-the-fact application to clinical judgments made years earlier, particularly where, as here, the government does not dispute that the therapy was actually delivered, was pursuant to physicians' orders, and that HCRMC incurred the cost of delivering the therapy. In an attempt to obfuscate these facts, the Department of Justice distills this massive amount of material into two words, "reasonable" and "necessary," and alleges in its Complaint that its own un-defined view of this standard trumps in all respects the physicians who ordered and the licensed therapists who delivered individualized care to each patient. What is clear, however, and ignored in the Complaint, is that CMS explicitly stated that clinical disagreements related to therapy assessments by SNFs are not false statements. *See* 42 C.F.R. § 483.20(j)(2).

As set forth herein, the Complaint fails as a matter of law for a number of reasons:

*First*, the alleged claims are not capable of falsity as a matter of law because they are matters of clinical disagreement over individualized assessments of treatment levels that are subject to differences of clinical opinion. These differences of clinical opinion cannot be deemed false absent an allegation, supported by facts, that a particular clinical professional violated an applicable legal or clinical standard of treatment upon which payment by the government was conditioned.

*Second*, applicable reimbursement rules and guidance fail to provide clear, objective standards as to what is reasonable and necessary. Without a clear standard to measure clinical determinations as to the frequency and duration of rehabilitation therapy, HCRMC's interpretations of ambiguous standards cannot establish the requisite scienter to submit objectively false claims.

*Third*, the government's general and conclusory allegations fail to satisfy applicable pleading standards to allege how claims submitted were inconsistent with any applicable law or standards and therefore ineligible or only eligible at lower reimbursement rates. The allegations relating to specific patients are devoid of any statutory or regulatory citation supporting what the government now asserts was required to support each claim. Summarily alleging that non-required documentation is absent or inadequate and as a result claimed services were not reasonable and necessary does not satisfy the pleading requirements for an FCA case.

*Fourth*, putting aside the fact that the allegations of "corporate pressure" are based on single sentences extracted and taken out of context from much larger documents, the Complaint fails to allege any link between these document extracts and the treatment of any specific patient or the submission of any specific claim. As such, these allegations do not support a reasonable inference that any particular claim submitted was false.

*Fifth*, the Complaint fails to plead scienter because it does not identify any individual who submitted a false claim, but rather impermissibly relies on allegations of collective corporate knowledge.

*Finally*, the Complaint fails to allege which of the four Defendants committed which purported unlawful acts, and instead treats the four Defendants as one without any regard for any specific acts alleged to have been performed by any single Defendant. Therefore, the Complaint fails to assert with particularity who allegedly violated the FCA or is liable under the common law claims.

## II. PROCEDURAL BACKGROUND

On January 9, 2009, Relator Christine Ribik filed under seal a *qui tam* complaint in this Court on behalf of the United States asserting claims under the FCA against HCR ManorCare, Inc. and Manor Care, Inc., as well as several HCRMC facilities. Dkt. 09-13, ECF No. 1; Compl.

¶ 23. On or about April 20, 2011, Ribik filed an amended complaint under seal, which added other related corporate entities and HCRMC facilities. Dkt. 09-13, ECF No. 23; Compl. ¶ 23. On August 17, 2010, Relator Marie Slough filed under seal a *qui tam* complaint in the United States District Court for the Eastern District of Michigan against HCR ManorCare, Inc. as well as an HCRMC SNF and several individual employees. Dkt. 14-1228, ECF No. 1; Compl. ¶ 25. On September 28, 2011 Relator Patrick Gerard Carson filed under seal a *qui tam* complaint in this Court on behalf of the United States asserting claims under the FCA against HCR ManorCare, Inc. and other related corporate entities. Dkt. 11-1054, ECF No. 1; Compl. ¶ 24. On June 13, 2012, this Court granted the government's request to consolidate Ribik's and Carson's actions. Compl. ¶ 24. On November 4, 2014, this Court granted the government's request to consolidate Slough's action with Ribik's and Carson's actions. Compl. ¶ 25.[3]

On April 10, 2015, the government filed its Complaint in intervention against the Defendants. Dkt. 09-13, ECF No. 84.

## III. APPLICABLE LAW

### A. THE FALSE CLAIMS ACT

The Complaint alleges claims against HCRMC pursuant to two provisions of the FCA: (1) presentation of false claims under § 3729(a)(1)(A); and (2) making or using a false record or statement material to a false claim under § 3729(a)(1)(B). To establish liability under the FCA, the Fourth Circuit has held that a plaintiff must plausibly allege four distinct elements in accordance with Fed. R. Civ. P. 12(b)(6) and 9(b): (1) a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) involved a claim made to the government for payment. *United States ex rel. Ahumada v. NISH,*

[3] None of the Defendants have been served with the Ribik, Slough or Carson complaints.

756 F.3d 268, 280-81 (4th Cir. 2014). A regulatory violation alone is insufficient to establish liability under the FCA because the FCA requires a "false statement or fraudulent course of conduct." *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014).

The requisite scienter under the FCA is "knowingly," which is defined as actual knowledge, deliberate ignorance, or reckless disregard. § 3729(b)(1). The collective knowledge of a company's agents cannot be used to establish scienter for an FCA violation. *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 918 n.9 (4th Cir. 2003). A company's scienter must be proven by demonstrating that a particular employee or officer acted knowingly. *Id.* at 919.

B. MEDICARE COVERAGE FOR REHABILITATION THERAPY UNDER MEDICARE PART A AND TRICARE

Medicare pays SNFs under a prospective payment system ("PPS") for beneficiaries covered by the Part A benefit that is based on expectations of required care. 42 U.S.C. § 1395yy(e). For rehabilitation therapy to be covered and reimbursed under Medicare Part A the beneficiary must be entitled to receive Medicare benefits, 42 U.S.C. § 1395c, 42 U.S.C. § 1395i–2, and the service must be "reasonable and necessary" either to diagnose or treat an illness or injury, or to improve functioning. 42 U.S.C. § 1395y(a)(1)(A). Rehabilitation therapy must be: (1) ordered by a physician; (2) performed by or under the supervision of professional or technical personnel, such as a physical or occupational therapist; and (3) rendered for a condition for which the patient received in-patient hospital services or for a condition that arose while receiving care in a SNF for which the patient received in-patient hospital services. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 409.31(b).[4]

Medicare Part A pays for SNF care for up to one hundred days after hospitalization "only

[4] The Complaint does not allege the absence of any of these three requirements.

if" a physician initially certifies, and recertifies every thirty days thereafter, the patient's need for skilled nursing and/or therapy services at a SNF. 42 U.S.C. § 1395f(a)(2)(B); 42 C.F.R. § 424.20. Regulations provide that each patient must be seen by a physician at least once every 30 days for the first 90 days after admission and at least every 60 days thereafter. 42 C.F.R. § 483.40(c). The physician's certification must indicate that the patient: (1) requires skilled nursing or skilled therapy services (or both) on a daily basis; (2) the daily skilled services can only be provided in a SNF on an in-patient basis; and (3) the services provided address a condition for which the patient received treatment during a qualifying hospital stay. 42 U.S.C. § 1395f(a)(2)(B); 42 C.F.R. §§ 409.31(b), 424.20(a).[5]

Medicare Part A pays SNFs a pre-determined rate for each day the patient receives skilled services. 42 C.F.R. § 413.335(a). This rate is based on the patient's condition as determined by the patient's classification into a Resource Utilization Group ("RUG"). 42 C.F.R. § 413.337(a)(iv). Each distinct RUG is intended to reflect the costs associated with providing skilled nursing and therapy services to patients with similar conditions or resource needs. *See* 63 Fed. Reg. 26,252, 26,265 (May 12, 1998). Medicare Part A places responsibility on licensed clinical professionals in each individual SNF to classify each patient's needs through periodic assessments on the 5th, 14th, 30th, 60th, and 90th day of the patient's Medicare Part A stay in the facility. 42 C.F.R. § 413.343. The periodic assessments are made by these clinical professionals and contemporaneously reported to the government on standardized forms using a tool known as the Minimum Data Set ("MDS").[6] 42 U.S.C § 1395i-3(b)(3)(A). These MDS

[5] The Complaint does not allege the absence of physician certifications.

[6] CMS changed the requirements of the MDS during the relevant time period. In 2006, CMS released the MDS Resident Assessment Instrument ("RAI") 2.0 Manual, which changed the MDS data points and instructions for completion. *See* Revised Long Term Care RAI User's

assessments report the patient's nursing and therapy needs (including the number of therapy minutes and disciplines to be provided), ability to perform activities of daily living, cognitive status, behavioral problems, and medical diagnoses based on the seven days preceding the assessment (the "look-back period"). 42 C.F.R. §§ 413.343, 483.20(b).[7] Using the information contained in the MDS, each patient is placed in a RUG level in accordance with the regulations which determines the amount of reimbursement. *See* 63 Fed. Reg. at 26,265. The five therapy-related RUG levels range from "Ultra High" ("UH"), where the patient is receiving at least 720 minutes of therapy per week in at least two disciplines, to "Low" ("RL"), where the patient is receiving 45 minutes per week of total therapy. 63 Fed. Reg. at 26,262

## IV. SUMMARY OF ALLEGATIONS

The Complaint alleges that, from October 1, 2006 through May 31, 2012, the Defendants[8] knowingly billed Medicare and TRICARE for rehabilitation therapy that was not reasonable and necessary. Compl. ¶¶ 4, 6. The Complaint alleges that HCRMC engaged in a nationwide plan to bill therapy services at UH RUG levels without regard to patients' actual needs. *Id*.

The Complaint alleges generally that HCRMC exerted corporate pressure on employees to meet UH billing targets and threatened SNF administrators and therapists if billing targets were not met. Compl. ¶¶ 7-9. The Complaint further alleges examples where employees

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Manual for the MDS Version 2.0, Chapter 1, § 2.9 (March 2006). In October 2009, CMS introduced RAI 3.0, which provided additional data points and instructions for completion of resident assessments and became effective on October 1, 2010. *See* MDS RAI 3.0 Manual, Chapter 2 (Oct. 2010).

[7] The Complaint does not allege the absence of required assessments, nor does it allege that therapy minutes not actually delivered were reported in the MDS.

[8] The Complaint names four defendants and repeatedly makes allegations as to all four as "HCR ManorCare," "Company," or "Defendants" without specifying particular conduct by each entity. *See, e.g.*, Compl. ¶¶ 2, 4, 6-8, 17, 88, 96, 99, 214, 216, 219.

purportedly set goals for billings at UH therapy levels. Compl. ¶¶ 100, 106-14. The Complaint alleges HCRMC communicated and enforced these goals through various means. Compl. ¶¶ 115-23. The Complaint does not allege a single example of enforcement of such goals through adverse employee action such as suspension or termination.[9] The Complaint cites two examples in which mid-level managers purportedly gave positive recognition to SNFs that billed Medicare at levels consistent with alleged corporate goals. Compl. ¶¶ 124-25. The Complaint concludes that corporate policies imposed pressure on facility personnel to provide more therapy than necessary based on revenue targets. Compl. ¶¶ 128-31.

The Complaint alleges "representative examples" of patients – Patients A through H – for which the government contends HCRMC billed for unreasonable and unnecessary services and attaches a chart of fifty alleged false claims submitted for those eight patients. *See* Compl. ¶¶ 146-48, 152-57, 171-73, 175-79, 182-95, 214. The Complaint does not include a single allegation linking the purported corporate pressure to these eight patients or fifty claims. Moreover, the Complaint is silent as to how physicians who ordered and certified the necessity of the services were involved in the purported plan. Indeed, ***none*** of the patients identified as representative examples received therapy at a facility mentioned in any of the alleged instances of corporate pressure. Further, while the Complaint contains conclusory statements that services were unreasonable or unnecessary, it is devoid of any reference to any federal regulation or guidance supporting this conclusion with respect to any single patient. The Complaint concludes that HCRMC knowingly submitted false claims for payment for therapy services that were ineligible for payment or were at a higher level than the patient was eligible. Compl. ¶ 214.

[9] The Complaint contains a single allegation that an unidentified therapist on an unknown date and time was counseled to follow discharge procedures, but it does not allege that the therapist provided unnecessary therapy. *See* Compl. ¶ 201.

## V. ARGUMENT

### A. PLEADING STANDARDS APPLICABLE TO ALL COUNTS

Under Federal Rule of Civil Procedure 12(b)(6), a complaint must "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ahumada*, 756 F.3d at 280 (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). A claim is facially plausible when it contains sufficient factual allegations for the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The plausibility standard "asks for more than a sheer possibility that a defendant has acted unlawfully," and so "where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility." *Id.* (internal quotations omitted). Legal conclusions and recitations of the elements of a cause of action fail to constitute well-pled facts. *Id*. at 681.

Claims brought under the FCA "must also meet the more stringent 'particularity' requirement of Federal Rule of Civil Procedure 9(b)." *Ahumada*, 756 F.3d at 280. Rule 9(b) requires that "an FCA plaintiff must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *Id.* (quoting *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008)). "More precisely, the complaint must allege 'the who, what, when, where and how of the alleged fraud.'" *Id.* (quoting *Wilson*, 525 F.3d at 379). Lack of compliance with Rule 9(b)'s pleading requirement is treated as a failure to state a claim under Rule 12(b)(6). *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 n.5 (4th Cir. 1999).

B. THE COMPLAINT FAILS TO STATE A PLAUSIBLE CLAIM FOR VIOLATIONS OF THE FCA UNDER FEDERAL RULES 12(B)(6) AND 9(B)

1. Counts I and II Fail as a Matter of Law Because Clinical Determinations are Not Capable of Objective Falsity Under the Applicable Regulatory Framework

The government cannot plead FCA liability as a matter of law without alleging that orders for therapy made by physicians and levels of treatment provided by licensed therapists were objectively false. *Wilson*, 525 F.3d at 377. "[I]mprecise statements or differences in interpretation growing out of a disputed legal question are not false." *Id.* (quoting *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999)). Further, claims are not false if "reasonable persons can disagree regarding whether the service was properly billed to the government." *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006). FCA liability cannot be based on the "government's post-hoc, general, and vague declarations" of what is medically necessary with respect to a claim. *See United States ex rel. Bunk v. Birkart Globistics*, No. 02–1168, 2014 WL 8037558, at *9 (E.D. Va. Dec. 24, 2014).

The core of the government's case is fundamentally flawed, because CMS's own regulations provide that clinical disagreements over assessments, and as such determinations of the frequency and duration of rehabilitation therapy, cannot constitute material and false statements. 42 C.F.R. § 483.20(j)(2); 62 Fed. Reg. 67,174, 67,202-03 (Dec. 23, 1997). Absent a specifically identified materially false statement and a specific physician or therapist who knowingly made that statement, these clinical disagreements cannot be false claims as a matter of law. *See United States ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 703 (N.D. Ill. 2012) (finding FCA allegations legally insufficient when they did not identify who was responsible for the allegedly false certification or why the certification was false).

The government has alleged only clinical disagreements over the reasonableness and necessity of amounts of therapy delivered, and, using the standard embodied in its own

regulations, has not alleged any "false" and "material" statements. The government does not allege that claims were false because the claimed services were not provided to beneficiaries by qualified therapists, that the patients were ineligible for skilled services, that a physician did not order the therapy provided to each individual patient, that HCRMC failed to comply with physician certification requirements, that HCRMC exceeded the level of rehabilitation therapy specified as medically necessary by physicians' certifications, or even that any physician committed or participated in a fraud by issuing orders for each individual patient. Moreover, because the government concedes that the services were actually delivered, there is no dispute that HCRMC bore the increased costs of delivering the services the government now says were unnecessary.

The determination of proper levels of rehabilitation therapy services require individualized clinical determinations by treating physicians and licensed therapists based on each patient's unique circumstances, and as such are subject to differences of clinical opinion.[10] *See* Medicare Benefit Policy Manual (CMS Pub. 102), Ch. 8, § 30.4 (". . . skilled therapy services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a qualified therapist are necessary for the performance of the rehabilitation services"). Indeed, Medicare regulations explicitly preclude "rules of thumb" to determine whether any particular therapy is "reasonable and necessary" and recognize that a certain type of rehabilitation therapy may be appropriate for one individual, but not for another. 42 C.F.R. § 409.32(b) ("A condition that does not ordinarily require skilled services may require them because of special medical complications."); 42 C.F.R.

[10] CMS has stated that when a facility obtains a physician's signature prior to billing Medicare, "the facility can be sure that the level of therapy for which it bills Medicare is the level the physician deems to be medically necessary." 64 Fed. Reg. 41,644, 41,660 (July 30, 1999).

§ 483.20 (outlining required resident assessments); Medicare Program Integrity Manual, Ch. 6, § 6.1 ("Rules of Thumb in the [Medical Review] process are prohibited.").

Under this regulatory framework, clinical determinations by licensed therapists in accordance with physician orders as to the specific type and duration of therapy are not capable of objective falsehood unless the government alleges, as it has not done here, that HCRMC billed for services not actually delivered. As recognized by CMS, the medical necessity of therapy services by its very nature involves fact-intensive, subjective determinations by clinicians who are actually treating the patients and exercising independent professional judgment based on their clinical knowledge of those patients. *See, e.g.*, 42 C.F.R. §§ 424.20(c), 483.25. Where reasonable professional minds may differ as to the determination of the type, duration, and frequency of the therapy treatment administered on each particular day, and the government does not dispute that the therapy was delivered to the patients and accurately described in the medical record, these opinions cannot be objectively false so as to be actionable under the FCA.[11] *See Harrison*, 176 F.3d at 792 ("Expressions of opinion are not actionable as fraud; fraud may only be found in expressions of fact which (1) admit of being adjudged true or false in a way that (2) admit of empirical verification.") (alterations omitted); *Wilson*, 525 F.3d at 377; *Geschrey*, 922 F. Supp. 2d at 703 (finding allegations of mere differences of opinion insufficient to support FCA liability where relators failed to allege "facts demonstrating that the certifying physician did not or could not have believed, based on his or her clinical judgment, that the patient was eligible

[11] Moreover, "[i]n determining medical necessity, courts employ what is known as the 'treating physician' rule, which provides that with respect to medical necessity, the judgment of the treating physician should be given 'extra weight' or 'a reasoned basis . . . [should be supplied] for declining to do so.'" *Prahbu*, 442 F. Supp. 2d at 1032; *see also State of N.Y. v. Sullivan*, 927 F.2d 57, 60 (2d Cir. 1991); *Gartman v. Sec'y*, 633 F. Supp. 671, 680-82 (E.D.N.Y. 1986) (the physician is the "key figure in determining utilization of health services").

for hospice care").[12]

In *Prabhu*, the government alleged that the defendant physician violated the FCA when he provided unnecessary medical procedures and failed to properly document the medical necessity of services. 442 F. Supp. 2d at 1016. The district court granted summary judgment in favor of the defendant and held that there was no falsity as a matter of law because "reasonable persons can disagree" regarding the therapy billing requirements, particularly absent specific guidelines from Medicare regarding the type of documentation to support the necessity of the procedure. *Id.* Here, licensed therapists making determinations as to the amount of therapy provided to individual patients were acting on orders of physicians that the government has not alleged were fraudulent. As such, reasonable minds may differ as to the medical necessity of subjective, individualized clinical determinations, and FCA liability cannot attach as a matter of law.[13] By alleging only disagreements over clinical determinations as to the level of therapy, the government has failed to allege a false statement as a matter of law.

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[12] *See also United States ex rel. Hockett v. Columbia/HCA*, 498 F. Supp. 2d 25, 65 n.29 (D.D.C. 2007) (acknowledging that "at some point, the question of whether a patient should be discharged becomes one of medical opinion, and that where reasonable medical minds might differ over the preferred course of treatment, FCA liability will be inappropriate"); *Mikes v. Straus*, 274 F.3d 687, 702 (2d Cir. 2001) (affirming dismissal of FCA action and explaining that although "a provider's choice of procedures [must] be 'reasonable and necessary,'" federal courts are not obligated to "step outside their primary area of competence and apply a qualitative standard measuring the efficacy of those procedures. The quality of care standard . . . is best enforced by those professionals most versed in the nuances of providing adequate health care.").

[13] *See e.g., United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x. 980, 983 (10th Cir. 2005) (holding that determination of the validity of an "intrinsically ambiguous" medical diagnosis was not "susceptible to proof of truth or falsity"); *United States ex rel. Milam v. Regents of the Univ. of Cal.*, 912 F. Supp. 868, 886 (D. Md. 1995) ("At most, the Court is presented with a legitimate scientific dispute . . . the legal process is not suited to resolving scientific disputes or identifying scientific misconduct."); *United States ex rel. Haight v. Catholic Healthcare W.*, No. 01-2253, 2007 WL 2330790, at *3 (D. Ariz. Aug. 14, 2007) ("Whether the quality of a particular tumor is sufficient to classify it as a 'subcutaneous tumor' involves a scientific judgment or opinion and cannot serve as the basis for an FCA claim.").

2. Counts I and II Fail Because Standards for Clinical Determinations of Rehabilitation Therapy Levels are Ambiguous, Preventing Defendants from Submitting an Objectively False Claim or Forming the Requisite Scienter

The government's FCA claims also fail because CMS has not established clearly-defined standards for what constitutes "reasonable and necessary" rehabilitation therapy, and as a result, the government cannot establish objective falsity and scienter as a matter of law. Claims are not false under the FCA unless services are furnished in violation of a controlling rule, regulation, or standard. *See, e.g., United States ex rel. Local 342 v. Caputo Co.*, 321 F.3d 926, 933 (9th Cir. 2003); *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 674-75 (5th Cir. 2003); *Prabhu*, 442 F. Supp. 2d at 1026 (explaining that in the absence of clear and objective regulatory criteria there is no basis to measure the truth or falsity of medical necessity and FCA liability cannot be established). Moreover, the government must allege that the defendant knew that each disputed charge was improper and therefore false. *See United States v. Newport News Shipbuilding*, 276 F. Supp. 2d 539, 561 (E.D. Va. 2003). The government cannot base fraud merely on its own interpretation of imprecise regulations, particularly where it never expressed dissatisfaction with a contractor's performance. *See United States ex rel. Badr v. Triple Canopy*, 775 F.3d 628, 635 (4th Cir. 2015); *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013) (where a regulation is unclear, a defendant's "reasonable interpretation of an ambiguity inherent in the regulations belies the scienter necessary to establish a claim for fraud under the FCA").

Based on an unknown standard, the Complaint alleges that certain minutes of therapy for certain patients were unnecessary and unreasonable. It is undisputed that HCRMC bore the costs of delivering this therapy. Under the governing legal framework for rehabilitation therapy claims, the Complaint fails to allege clear and objective regulatory standards for the type, amount, frequency, and duration of rehabilitation therapy services such that claims for such

services are capable of falsity under the FCA.

Although the applicable federal programs reimburse certain rehabilitation therapy services that are reasonable and necessary for the treatment of the patient's condition, 42 U.S.C. § 1395y(a)(1)(A), Congress *chose not to define* "reasonable" or "necessary" through statute, and the government similarly chose not to do so by regulation. *See* 54 Fed. Reg. 4302, 4304, 4308, 4312 (Jan. 30, 1989) ("Current regulations are *general* and *we have not defined the terms 'reasonable' and 'necessary,'* nor have we described in regulations a process for how these terms must be applied.") (emphasis added); *see also Prabhu*, 442 F. Supp. 2d at 1026 ("CMS has not delineated what constitutes 'medically indicated' and 'necessary' items or services."). Instead the government placed responsibility for contemporaneous treatment decisions on licensed therapists acting pursuant to physicians' orders to determine what is "reasonable and necessary" based on "the perspective of the patient's condition when the services were ordered and what was, at that time, reasonably expected to be appropriate treatment for the illness or injury." Medicare Benefit Policy Manual, Ch. 8, § 30.2.2.1. The government has explicitly acknowledged that the standard applicable to SNFs "does not always lend itself to easy, ***objective evaluation***." 65 Fed. Reg. 14,289, 14,293 n.26 (Mar. 16, 2000) (emphasis added); *see also* Settlement Agreement, *Jimmo v. Sebelius*, No. 11-0017 (D. Vt. Oct. 16, 2012), ECF. No. 82 (attached as Exhibit C) (government's acknowledgement that the standard for determining medical necessity for skilled therapy services is ambiguous and agreement to clarify the standard).[14]

[14] The absence of detailed standards is apparent from the Complaint. Although the government purports to assert fraud based on knowing violations of eligibility standards, the government's examples instead rely on alleged inadequate documentation as a proxy for fraud, even where no specific documentation requirements exist. For example, the government alleges fraud because

HCRMC could not have possessed requisite scienter to "knowingly" submit a false claim, because there were no objective standards for these individual clinical determinations regarding the precise type and amount of therapy to be delivered on any given day, particularly when clinical professionals may have legitimate disagreements.[15] Even if the government's allegations that HCRMC pressured and encouraged therapists to maximize the amount of therapy delivered are taken as true, when measured against an imprecise and subjective standard purposely left vague by Congress and CMS, the FCA cannot apply.[16] FCA liability only attaches to "lies" and a defendant does not knowingly submit a false claim when his conduct is consistent with a reasonable interpretation of ambiguous regulations.[17] HCRMC's alleged plan to maximize

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HCRMC failed to document the "types of services" provided in a group setting, or how those group services specifically "related to [a patient's] plan of care," Compl. ¶ 146, but the Complaint cites to no statute or regulation because no such documentation requirements exist. Similarly, there is no statute or regulation requiring a therapist to document "how modalities related to the plan of treatment and attainment of goals," as is alleged. Compl. ¶ 182.

[15] Indeed, the Medicare program recognizes that clinical diagnoses may elicit differing opinions. For example, the program explicitly provides and reimburses for participants to obtain "second opinions" and even third opinions prior to surgery or other major procedures. Medicare Benefit Policy Manual, Ch. 15, § 30.D ("In the event that the recommendation of the first and second physician differs regarding the need for surgery (or other major procedure), a third opinion is also covered.").

[16] The reason the Complaint does not meet the FCA's scienter requirement is apparent from the government's arbitrary allegations as to reasonable and necessary amounts of therapy. The Complaint fails to allege why the government now disallows a certain number of minutes for each patient; as to Patient F, why 969 minutes instead of 968? (Compl. ¶ 189); as to Patient B, why 360 minutes instead of 355? (Compl. ¶ 154). HCRMC is left to guess when therapists began to engage in fraud. Was it one minute over the government's retroactive determination of the alleged correct level of therapy? When did each individual therapist know they had crossed the government's invisible fraud line?

[17] *See, e.g., Ketroser,* 729 F.3d at 832; *United States ex rel. Hixson v. Health Mgmt. Sys. Inc.*, 613 F.3d 1186, 1191 (8th Cir. 2010) (finding that a defendant's reasonable interpretation of the law, even if opportunistic, cannot demonstrate the requisite scienter for an FCA violation); *Hagood v. Sonoma Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996) (affirming dismissal of an FCA action and explaining that "[t]o take advantage of a disputed legal question, as may have happened here, is to be neither deliberately ignorant nor recklessly disregardful"); *Prahbu,* 442

reimbursement under undefined standards based on a reasonable interpretation of ambiguous rehabilitation therapy regulations cannot meet the scienter requirement of the FCA, and in fact was nothing more than engaging in prudent business practices. *See Lawson*, 2015 WL 1541491, at 30-33.[18] As a result, the necessary elements of falsity and scienter cannot extend to the circumstances of this case, which are simply differences of opinion regarding interpretation of intentionally vague laws and regulations.[19]

3. Counts I and II Should Be Dismissed Because the Alleged Examples of False Claims Do Not Satisfy Pleading Standards Under Federal Rules 12(b)(6) and 9(b) to Establish the Submission of a Single False Claim

The government's claims should be dismissed because the Complaint fails to allege facts with particularity as to the falsity of any claims submitted based on an objective violation of an established law or regulation. Beyond repeating the legal conclusion that certain services were

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F. Supp. 2d at 1016; *United States ex rel. Swafford v. Borgess Med. Ctr.*, 98 F. Supp. 2d 822, 831-32 (W.D. Mich. 2000) (where the regulatory terms were undefined and ambiguous and the plaintiff's position "devolves to a dispute over the meaning of the terms governing the delivery of the professional component of physicians services . . ." there was no violation of the FCA because a "legal dispute is . . . insufficient" to establish FCA liability); *United States v. Krizek*, 859 F. Supp. 5, 9-10 (D.D.C. 1994) (ruling that because the key term in the billing code was undefined and hence "ambiguous," the government could not state an FCA cause of action), *aff'd in part, rev'd in part*, 111 F.3d 934 (D.C. Cir. 1997); *accord U.S. Dep't. of Transp. ex rel. Arnold v. CMC Eng'g*, 567 F. App'x 166 (3d Cir. 2014) (holding that where a government contract was ambiguous, there is no basis for a defendant to "knowingly" submit a false claim).

[18] Although HCR ManorCare disputes that it exerted corporate pressure to improperly increase and maximize reimbursement, the goal of maximizing reimbursement does not support an FCA violation. *See United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 528 (6th Cir. 2012) (reversing and remanding judgment for government in FCA case alleging that defendants dialysis provider and related entities acted in violation of controlling statutes and regulations by taking advantage of Medicare regulatory scheme to increase profits by explaining: "[w]hy a business ought to be punished solely for seeking to maximize profits escapes us").

[19] Furthermore, the government has a remedy for issues like this: a straight-forward administrative process to disallow payment for claims that Medicare Administrative Contractors determine are not reasonable and necessary, and to seek recovery for overpayments. 42 C.F.R. § 405(I) (outlining the process for determining if a claim is payable and the subsequent appeals process); 42 U.S.C. § 1395gg (governing the recovery of overpayments).

not reasonable and necessary, the Complaint fails to articulate ***how*** the services were allegedly "ineligible" or only "eligible for a lower level of payment than claimed." *See* Compl. ¶ 214. The Complaint also fails to allege *what* standard was applied to reach this legal conclusion and who other than the prosecutors made this determination. Services are not unreasonable and unnecessary just because the Department of Justice alleges that they are. Rather, to satisfy applicable pleading standards, the government must allege facts sufficient to plausibly establish that a defendant knowingly submitted a false claim in violation of an established law or regulatory standard. *United States ex rel. Frazier v. IASIS Healthcare Corp.*, 812 F. Supp. 2d 1008, 1016-18 (D. Ariz. 2011) (dismissing FCA complaint based, in part, on allegations of medically unnecessary procedures where relator did not plead facts showing why the procedures performed were unnecessary or that the physician knew the procedure was medically unnecessary at the time it was performed); *Maa v. Ostroff*, No. 12-0020, 2013 WL 1703377 (N.D. Cal. Apr. 19, 2013) (dismissing FCA complaint where allegations that procedures were unreasonable and unnecessary did not meet heightened pleading standards required for FCA claims).

The Complaint fails to provide factual allegations as to *how* any claims submitted by any Defendant run afoul of any applicable law or regulatory standard. With respect to Patients A through H, the Complaint follows a formulaic pattern of alleging an over-simplified version of each patient's medical condition, the amount and type of therapy provided, arbitrary deduction of a number of minutes based on the government's undefined standard, and a conclusory statement that a certain amount of therapy was unnecessary and unreasonable. *See* Compl. ¶¶ 146-48 (Patient A), 152-58 (Patient B), 171-73 (Patient C), 175-79 (Patient D), 182-84 (Patient E); 186-89 (Patient F), 191-94 (Patient G), 195 (Patient H). But the Complaint fails to allege an

objective standard against which the Department of Justice made these determinations, and instead invents purported documentation requirements that do not exist in any statute or regulation. Further, the Complaint does not allege that any of the therapy was provided absent a physician's order or certification. These bare and conclusory allegations as to Patients A through H fail to satisfy applicable pleading standards, because they do not articulate particular facts that plausibly and with particularity establish that the therapy provided and billed was not reasonable and necessary.

For example, the Complaint alleges that all group therapy minutes provided to Patient A between June and August of 2011 were unnecessary or unreasonable because the therapists did not document the types of services that were provided in the group setting or how the group therapy related to Patient A's plan of care. Compl. ¶¶ 146-47. But the Complaint ignores the law; prior to October 1, 2011, Medicare payment rules did not require therapists to document the types of services provided in a group therapy setting or how the group therapy services related to the patient's plan of care. *See* 76 Fed. Reg. 48,486, 48,512-17 (August 8, 2011). Without such a documentation requirement, there cannot be a violation of the FCA for failure to have such documentation. *See Prahbu*, 442 F. Supp. 2d at 1016; *Geschrey*, 922 F. Supp. 2d at 703 (finding to be groundless allegations of fraud based on the general charge that patients were certified as terminally ill without being seen by a physician where a face-to-face examination was not required by the relevant regulations).

As to Patient B, the Complaint alleges that during two separate admissions, more therapy was provided during assessment periods than during non-assessment periods. Compl. ¶ 153. The Complaint then alleges that because the therapists did not document clinical reasons to support an increase during assessment periods or reduction post-assessment, a seemingly

arbitrary number of therapy minutes were unnecessary and unreasonable, thereby rendering the related claims false. Compl. ¶¶ 153, 156-57. However, no statute or regulation requires explanations for fluctuations in minutes between assessment and non-assessment periods, and the Complaint concedes that any fluctuations were accurately recorded and apparent when the claim was paid.

As to Patients C and D, the Complaint essentially alleges that these patients were too ill or close to death to need or legitimately receive therapy. Compl. ¶¶ 171-79.[20] But again, the Complaint cites no law or regulation that requires therapy to cease in these circumstances, nor does it plausibly plead that therapy should have ceased for these patients. In fact, the government is wrong to allege that Patient D "was to receive hospice care only" and was ineligible for rehabilitation therapy. Even if the physician made a hospice referral, under applicable Medicare law and regulations, the beneficiary (or representative if the individual is physically or mentally incapacitated) has to affirmatively elect the hospice benefit. 42 U.S.C. § 1395d(d)(1); 42 C.F.R. § 418.24. The government has not alleged that either Patient C or D elected the hospice benefit and that unnecessary rehabilitation continued thereafter.

As to Patients E and F, the Complaint alleges unnecessary and unreasonable therapy because the medical records did not include documentation regarding indication for use of certain therapeutic methods or how those methods related to the plan of treatment. Compl. ¶¶ 182-84, 187-89. However, the Complaint is devoid of any allegations that the use of these therapeutic methods as part of rehabilitation therapy is inconsistent with any rule or regulation or that there is any specific requirement for documenting the decision to use a particular method.

[20] Here the government has the benefit of knowing Patient C's date of death, a fact that was known only to God at the time therapy was delivered.

To the contrary, CMS regulations expressly provide that therapeutic treatments such as ultrasound, shortwave and microwave therapy, hot packs, and infrared treatments that require the skills of a qualified physical therapist qualify as skilled therapy services. 42 C.F.R. § 409.33(c)(6)-(7). Despite what the government alleges, no statute or regulation requires documentation regarding "indication for use of modalities" or "how modalities related to plan of treatment and attainment of goals" as alleged. Compl. ¶ 182.

With respect to Patients G and H, the Complaint alleges without any detailed explanation that each patient received unnecessary and unreasonable speech therapy. The government does not allege why Patient H's speech therapy was unreasonable and unnecessary, nor does it allege the absence of physician's order for Patient H. While the Complaint alleges Patient G did not have an order for speech therapy upon admission to the SNF from the hospital, there is no requirement that physician orders exist at the time of admission, nor do the regulations preclude a physician from updating orders after the date of admission.[21] As there are no plausible allegations that Patients G and H lacked orders for speech therapy, the Complaint is devoid of any factual allegation from which to reasonably infer that speech therapy (or other therapy) minutes were not reasonable or necessary.

[21] In fact, Patient G's medical record clearly shows that on July 13, 2009, a nurse at the SNF called Patient G's physician to request orders for a swallow and speech therapy evaluation and speech therapy for cognition, and that twenty minutes later, those orders were received. In response, on July 14, 2009, an order for speech therapy was completed, defining the treatment plan, frequency and duration, and was later signed by a physician. These documents, which are in the government's possession, are attached as Exhibit D, and have been redacted to protect personal and protected health information of Patient G. The Complaint references Patient G's medical record as integral for the basis for alleging the claim was false and therefore the documents are deemed part of the Complaint and may be considered on a Rule 12(b)(6) motion without converting it to a motion for summary judgment. *See Am. Chiropractic Ass'n v. Trigon Healthcare, Inc.*, 367 F.3d 212, 234 (4th Cir. 2004).

4. Counts I and II Should be Dismissed Because the Complaint Does Not Allege Any Causal Link Between the Alleged Corporate Scheme and the Submission of a Single False Claim

Despite the general allegations of a nationwide corporate plan to defraud the Medicare program over the course of nearly six years, the Complaint fails to link the alleged "corporate pressure" to any particular false claim. *See United States v. Kernan Hosp.*, 880 F. Supp. 2d 676, 687–88 (D. Md. 2012) (dismissing the government's complaint because it "fails to provide the crucial link between the alleged scheme and ultimate [FCA] liability"). Merely asserting facts related to a defendant's alleged misconduct is not enough; a complaint must allege that false claims were submitted for government payment as a result of the defendant's alleged misconduct. *United States ex rel. Rost v. Pfizer, Inc*., 507 F.3d 720, 732-33 (1st Cir. 2007); *Sanderson v. HCA-The Healthcare Co*., 447 F.3d 873, 877 (6th Cir. 2006) (the FCA "does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe"); *United States ex rel. Totten v. Bombardier Corp*., 286 F.3d 542, 551 (D.C. Cir. 2002) (noting that the FCA "attaches liability, not to underlying fraudulent activity, but to the 'claim for payment.'").

The Complaint fails to plead facts sufficient to support a link between alleged corporate practices and "specific, identifiable claims [that] actually were presented to the government for payment." *United States ex rel. Nathan v. Takeda Pharm. N.A., Inc.*, 707 F.3d 451, 458 (4th Cir. 2013). Although the Complaint outlines alleged "corporate pressure" based on portions of documents taken out of context relating to various performance goals and targets, the government does not in any way or instance connect these allegations to actual claims for payment that were submitted to the government. The Complaint does not allege that any physician or therapist who treated any of the patients listed in the Complaint ever read, saw or

had access to any of the information in these documents. Instead, the Complaint simply contains the general and conclusory assertion that false claims were submitted "as a direct result" of such "corporate pressure." Compl. ¶¶ 97-98. These general and conclusory assertions are insufficient to satisfy Rule 9(b), and by extension Rule 12(b)(6). *See Iqbal*, 556 U.S. at 678.

The government may not rely on a theory of liability under the FCA premised on the assertion that such corporate pressure broadly led to fraud. Rather, to satisfy Rule 9(b) and the general plausibility standard of *Iqbal*, the government must allege with particularity that specific false claims were presented to the government for payment as a direct and proximate result of the alleged corporate scheme. *Nathan*, 707 F.3d at 457. The government fails to allege any particular facts that the purported "corporate pressure" directly and proximately resulted in the submission of fraudulent claims with respect to these eight beneficiaries or any other. *See United States ex rel. Hagood v. Riverside Healthcare Ass'n, Inc.*, No. 11-0109, 2015 WL 1349982, at *9 (E.D. Va. Mar. 23, 2015) (dismissing FCA complaint in part under Rule 9(b) for failing to connect the alleged fraudulent scheme with any specific claim submitted for payment).

5. Counts I and II Should be Dismissed Because the Complaint Fails to Plead the Requisite Scienter of Any Individual with Respect to Any of the Alleged False Claims

The Complaint fails to sufficiently plead scienter because it does not allege that any individual submitted a false claim with the requisite scienter. A company's scienter for FCA purposes can only be proven by demonstrating that a particular employee or officer acted knowingly. *See Harrison*, 352 F.3d at 919. The Complaint fails to allege that any particular therapist provided allegedly unnecessary or unreasonable services to Patients A through H, or any other patient, and acted with knowledge, reckless disregard, or deliberate ignorance that the services were unnecessary or unreasonable. This fundamental defect in the Complaint is apparent from the government's failure to identify a single individual who actually filed any

claim on behalf of HCRMC. Instead the government resorts to "information and belief" to allege that unidentified employees used a billing system called "ePremis" to file claims, Compl. ¶ 92, without alleging how this system operates, who enters the data into the system, and who attests to reasonableness and necessity of treatments.[22]

The Complaint's failure to allege that any particular therapist knowingly provided therapy in violation of a legal or professional standard is fatal to the government's claims.[23] Allegations in the Complaint about statements made by low or mid-level personnel located in random and disparate geographical locations are insufficient, because there is no allegation that the alleged statements were known by any person providing any of the examples of allegedly unnecessary services. For example, with respect to group therapy, the allegations in paragraph 140 regarding statements made by an Eastern Division Regional Rehab Manager on an unidentified date in 2008, cannot support a finding of knowledge as to the allegedly unnecessary or unreasonable group therapy provided to Patient A, who was a patient in 2011 and 2012 in a facility in Kansas, which is not alleged to be (and is not) a part of the Eastern Division. Similarly, the statements in paragraph 144, allegedly made by unidentified Directors of Rehabilitation in a facility in Texas and an unidentified facility in the West Division on unidentified dates, cannot support a finding of knowledge relating to services provided to Patient A at HCRMC's facility in Topeka, Kansas.

Moreover, failing to identify in the Complaint the individuals who formulated the alleged

[22] Courts have cautioned against reliance on information-and-belief pleading in the FCA context, particularly with respect to the submission of claims. *See United States ex rel. Palmieri v. Alpharma*, No. 10-1601, 2014 WL 1168953, at *11 (D. Md. Mar. 21, 2014); *United States ex rel. Martinez v. Va. Urology Ctr.*, No. 09-442, 2010 WL 3023521, at *5 (E.D. Va. July 29, 2010).

[23] The Complaint does not even allege that a single therapist delivered each mode of therapy to each patient; leaving it unknown whether the government alleges that where multiple therapists delivered a single mode of therapy they were all in cahoots to fraudulently increase the minutes.

plan and knowingly filed the alleged false claims for reimbursement is fatal to the government's Complaint. Collective knowledge of unnamed individuals cannot, as a matter of law, form the basis for proof of scienter in an FCA case because, "it effectively imposes liability, complete with treble damages and substantial civil penalties, for a type of loose constructive knowledge that is inconsistent with the Act's language, structure and purpose." *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274 (D.C. Cir. 2010); *see also Harrison*, 352 F.3d at 918 n.9 (recognizing the problematic implications of applying the collective knowledge theory in an FCA case); *United States ex rel. Dyer v. Raytheon*, No. 08-10341, 2012 WL 5348571, at *26 (D. Mass. Sept. 23, 2013) (the government must prove that a single individual acting on behalf of the defendant had the requisite knowledge and approved the knowing false claims). The Complaint fails to meet these standards because it fails to allege facts necessary to conclude who acted in violation of law.

C. THE COMPLAINT FAILS TO STATE A CLAIM UNDER FEDERAL RULE 9(B) BECAUSE IT GROUPS TOGETHER THE DEFENDANTS' ALLEGED CONDUCT AND FAILS TO ALLEGE WHO COMMITTED WHICH ACTS

In addition to the legal deficiencies set forth above, the Complaint improperly attempts to blur together the alleged conduct of four legally distinct entities. By failing to allege facts as to the submission of a false claim by any particular Defendant, the Complaint fails to state a claim against any Defendant. When a complaint purports to allege violations of the FCA or fraud against multiple defendants, "[d]efendants cannot simply be grouped together without specification of which defendant committed which wrong;" rather, "Rule 9(b) requires that a complaint set forth with particularity each defendant's culpable conduct." *United States ex rel. Ahumada v. Nat'l Ctr. for Emp't of the Disabled*, No. 06-0713, 2013 WL 2322836, at *3-4 (E.D. Va. May 22, 2013), *aff'd* 756 F.3d 268 (4th Cir. 2014); *Adams v. NVR Homes, Inc.*, 193 F.R.D. 243, 250 (D. Md. 2000) (finding that a complaint fails to meet Rule 9(b) when it alleges fraud

against multiple defendants without identifying each defendant's participation in the alleged fraud).

While the Complaint concedes each Defendant is a separate and distinct entity, Compl. ¶¶ 26-29, it contains only generalized allegations collectively against all Defendants and groups the four distinct entities into one. Throughout the Complaint, it collectively refers to all four entities as "HCR ManorCare," "Company," or "Defendants" without specifically alleging which entity is responsible for which act. *See* Compl. ¶ 2. The Complaint's failure to identify with particularity which Defendant committed which alleged act is fatal, and warrants the dismissal of all counts against the Defendants. *See Apple v. Prudential-Bache Secs., Inc.*, 820 F. Supp. 984, 987 (W.D. N.C. 1992), *aff'd* 993 F.2d 228 (4th Cir. 1993) (dismissing a complaint that "groups defendants together without specifying which defendant committed which wrong"). Merely alleging that the entities were related, shared personnel, were involved in certain personnel decisions, and filed a joint tax return do not establish that any of the Defendants violated the FCA.[24] Accordingly, the Complaint fails to allege *who* engaged in which purported unlawful act.

D. THE COMPLAINT FAILS TO STATE COGNIZABLE CLAIMS FOR UNJUST ENRICHMENT (COUNT III) AND PAYMENT BY MISTAKE (COUNT IV)

The government's common law claims for unjust enrichment (Count III) and payment by mistake (Count IV) arise from the same factual allegations underlying its FCA claims. For the reasons stated above, Counts III and IV should be dismissed.

Furthermore, the factual underpinnings of these repetitious claims are identical to those underlying the government's FCA claims. As a result, Counts III and IV are subject to heightened pleading requirements under Rule 9(b) – which the government fails to meet –

[24] For example, with respect to Defendant Manor Care, the Complaint alleges only that Manor Care was a predecessor in interest to defendant HCR ManorCare but nothing whatsoever as to its role in the alleged fraudulent scheme or submission of any false claims. *See* Compl. ¶ 27.

warranting dismissal of these claims. *See, e.g., Lawson*, 2013 WL 5816501, at 33-34 (dismissing payment by mistake and unjust enrichment claims based on alleged unreasonable, unnecessary and/or unskilled therapy for failure to satisfy Rule 9(b)); *United States ex rel. Tillson v. Lockheed Martin Energy Sys., Inc.*, No. 00-0039, 2004 WL 2403114, at *27 (W.D. Ky. Sept. 30, 2004) (finding that the government's unjust enrichment claim failed under Rule 9(b) for the same reason its FCA claim failed); *Silverman Partners, L.P. v. First Bank*, 687 F. Supp. 2d 269, 288 (E.D.N.Y. 2010) ("[U]njust enrichment must be pled with specificity when the underlying acts are allegedly fraudulent.").

Finally, the government attempts to hold all HCRMC Defendants liable for unjust enrichment, yet alleges that only HCR ManorCare, Inc. received alleged improper reimbursements. *See* Compl. ¶ 222. Curiously, the government asserts its payment by mistake claim against HCR ManorCare Services, not HCR ManorCare, Inc. These allegations are inconsistent, unsupported by the facts alleged, and irreconcilable. Without properly alleging which entity the government paid, these claims cannot survive. *Purcell*, 520 F. Supp. 2d at 173 (unjust enrichment and payment by mistake "only lie[] against a defendant to whom a benefit (money) was actually paid").

## VI. CONCLUSION

WHEREFORE, for the foregoing reasons, Defendants respectfully request that the Court dismiss the Complaint pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6).

Dated: July 7, 2015

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 7th day of July, 2015, the foregoing was electronically filed with the clerk of court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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